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ATTORNEYS FOR PLAINTIFF(S)

MARIA MENDEZ 1218 Paoli Pike West Chester, PA 1938 Plaintiff(s), -VS- RAHUL V. SHAH, M.D. 298 S. Delsea Drive Vineland, NJ 08360; -AND- PREMIER ORTHOPAEDIC ASSOCIATES SURGICAL CENTER, LLC 525 State Street Elmer, NJ 08318 -AND- PREMIER ORTHOPEDIC ASSOCIATION OF SOUTH JERSEY 298 S. Delsea Drive Vineland, NJ 08360 -AND- IAN R. GRAY, PA-C 298 Delsea Drive Vineland, NJ 08360 -AND- SOUTH JERSEY HEALTHCARE DBA/TA SJH ELMER HOSPITAL 501 West Front Street Elmer, NJ 08318 -AND- MEDTRONIC SOFAMOR DANEK USA, INC. 2600 Sofamor Danek Drive Memphis, TN 38132 -AND- MEDTRONIC SPINE, LLC 2600 Sofamor Danek Drive Memphis, TN 38132 -AND- MEDTRONIC USA, INC. 710 Medtronic Parkway Minneapolis, MN 55432 -AND- MEDTRONIC, INC. 710 Medtronic Parkway Minneapolis, MN 55432 -AND- JOHN DOE CORPORATIONS A through J, -AND-JOHN DOES A through J, (fictitiously named entities and persons whose identities are unknown to Plaintiff), Defendant(s).	UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY Docket No. _____ COMPLAINT AND JURY DEMAND: MEDICAL NEGLIGENCE

Plaintiff MARIA MENDEZ, by and through her undersigned attorney, by way of Complaint, states as follows:

THE PARTIES:

1. Plaintiff MARIA MENDEZ is an adult individual residing at the address in the caption and a citizen of the Commonwealth of Pennsylvania for purposes of diversity jurisdiction.

2. Defendant RAHUL V. SHAH, M.D., is an adult individual whose principal place of business is at the address in the caption, where he may be served with summons, and who, at all times relevant herein, was a licensed physician in the State of New Jersey and held himself out to the public as a specialist in orthopedic surgery in the State of New Jersey, and who is a citizen of the State of New Jersey for purposes of diversity jurisdiction.

3. Defendant PREMIER ORTHOPAEDIC ASSOCIATES SURGICAL CENTER, LLC, is a limited liability company or other business entity established under the laws of the State of New Jersey, with a principal place of business at the address in the caption, and which was the actual or ostensible employer, master or principal of certain individual persons as set forth below, and which may be served with summons at the address in the caption.

4. Defendant PREMIER ORTHOPAEDIC ASSOCIATES OF SOUTH JERSEY is a corporation, professional association, or other business entity established under the laws of the State of New Jersey, with a principal place of business at the address in the caption, and which was the actual or ostensible

employer, master, or principal of certain individual persons as set forth below, and which may be served with summons at the address in the caption.

5. Defendant IAN R. GRAY, PA-C, is an adult individual whose principal place of business is at the address in the caption, where he may be served with summons, and who, at all times relevant herein, was a certified physician's assistant in the State of New Jersey, and who is a citizen of the State of New Jersey for purposes of diversity jurisdiction.

6. Defendant SOUTH JERSEY HEALTHCARE doing business as SJH ELMER HOSPITAL is a corporation or other business entity organized under the laws of the State of New Jersey, which owns, operates and manages the SJH Elmer Hospital, which has a principal place of business at the address in the caption, and which may be served with summons at the address in the caption.

7. Defendant MEDTRONIC SOFAMOR DANEK USA, INC., is a corporation or other business entity organized under the laws of the State of Tennessee, with a principal place of business at the address in the caption, and which may be served with summons at the address of its registered service agent in the State of New Jersey as follows: The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628.

8. Defendant MEDTRONIC SPINE, LLC, is a limited liability company, corporation or other business entity organized under the laws of the State of Delaware, with a principal place of business at the address in the caption and which may be served with summons at the address of its registered service agent in the State

of New Jersey as follows: The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628.

9. Defendant MEDTRONIC USA, INC., is a corporation or other business entity organized under the laws of the State of Minnesota, with a principal place of business at the address in the caption, and which may be served with summons at the address of its registered service agent as follows: The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628.

10. Defendant MEDTRONIC, INC., is a corporation or other business entity organized under the laws of the State of Minnesota, with a principal place of business at the address in the caption, and which may be served with summons at the address of its registered service agent as follows: The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628.

11. Defendant(s) JOHN DOE CORPORATIONS A through J, are fictitiously named corporations or other business entities whose identities are not presently known to the Plaintiff Maria Mendez and may be known to the named Defendants which participated in the care and treatment of Plaintiff in one or more of the following capacities: actual or ostensible employers, masters, staffing agencies, or principals of any of the named Defendants; suppliers or distributors of goods and/or services to the Plaintiff during her care and treatment at the times complained of herein; manufacturers, sellers, designers, packagers, marketers, or distributors of certain surgical products or supplies implanted, replaced, or removed from the Plaintiff; or in any other way participated in the care and treatment of the Plaintiff and

who are or may be liable to the Plaintiff for injuries and harm and damages caused to her as alleged hereinafter.

12. Defendant(s) JOHN DOES A through J, whether male or female, are fictitiously named individuals whose identities are not presently known to the Plaintiff Maria Mendez and who may be known to the named Defendants, who participated in the care and treatment of Plaintiff in one or more of the following capacities: health care assistants or professionals; pre-operative, operative or recovery room personnel; nurses, nurses' assistants or CNA's; actual or ostensible agents, servants and/or employees of any of the named Defendants or any of the John Doe Corporations or individuals, whether known or unknown to the Plaintiff at the present time, or who otherwise participated in the care and treatment of the Plaintiff, including the provision or supply of any services or products, and who are or may be liable to the Plaintiff for the injuries and harm and damages caused to her under the theories of liability as alleged hereinafter.

JURISDICTION AND VENUE:

13. This action is brought under 28 U.S.C. § 1332(a), diversity of citizenship and amount in controversy, in that the Plaintiff is a citizen of the COMMONWEALTH OF PENNSYLVANIA and the Defendants are citizens of the STATES OF NEW JERSEY, TENNESSEE, DELAWARE, AND MINNESOTA, and the amount in controversy exceeds the jurisdictional limit exclusive of interest and costs.

14. Venue is proper in this Court under 28 U.S.C. § 1391(a) in that the accident or incidents occurred within this judicial district, and the Defendants may be

served with summons in this district, and furthermore, the MEDTRONIC DEFENDANTS maintain a national and global marketing and distribution system whereby plaintiff's physicians/hospital or other organizations purchased the subject medical or surgical products directly or indirectly from the manufacturer(s) and/or distributor(s) and the manufacturer(s) shipped the products to the physician(s)/hospital in New Jersey.

THE MEDICAL EVENTS AND PERSONAL INJURIES

15. Prior to the events complained of, Plaintiff MARIA MENDEZ came under the care and treatment of Defendant RAHUL V. SHAH, M.D. (hereinafter "Shah" or "Dr. Shah"), an orthopedic surgeon, for chronic severe back pain which radiated into her lower extremities and impaired her mobility.

16. Defendant Shah was aware of Plaintiff's medical history of a previous back surgery consisting of laminectomy and fusion in the low back in or about 2007.

17. Prior to the subject surgery in March, 2011, Plaintiff underwent nonoperative treatment including medications, epidural injections, and activity modification, which were not sufficiently effective to reduce her pain.

18. Defendant Shah diagnosed Plaintiff with spinal stenosis and spondylolistheses at L4-L5 and L5-S1.

19. Imaging studies showed post-surgical defects at L4-L5 from the previous laminectomy in or about 2007 and Grade I spondylolisthesis of L5 on S1, facet arthropathy and mild listhesis as well as foraminal narrowing and mild degenerative disk disease at both levels, mild distortion of the thecal sac.

20. On or about March 21, 2011, Defendant Shah, reportedly assisted by Defendant Ian R. Gray, PA-C, and no other qualified surgeon or physician, performed the following procedures on Plaintiff: an L4-L5 and L5-S1 lumbar laminectomy revision bilaterally; lumbar instrumentation segmental at L4, L5 and S1; lumbar fusion posterolateral at L4-L5 and L5-S1; lumbar autograft and BMP application; posterior interbody lumbar fusion level L4-L5, L5-S1; application of allograft on anterior lumbar application and biomechanical cevise interspaces; intraoperative fluoroscopy, and neurological monitoring with EMG and SSEP under general anesthesia.

21. "Stenosis" was listed among intraoperative findings.

22. During the above procedures, Dr. Shah used the following medical-surgical products: Capstone Spinal System, InFuse Bone Graft, CD Horizon Legacy screws, Cancellous chips, and surgical putty among others; these devices were designed, manufactured, assembled, packaged, labeled, marketed, distributed, supplied, and/or sold by the MEDTRONIC DEFENDANTS and/or contractors or subcontractors or others in the chain of distribution established and contracted by the MEDTRONIC DEFENDANTS individually or in combination.

23. It is believed and therefore averred that the healthcare Defendants—Shah, Premier Orthopaedic Associates, Premier Orthopedic Associates, Gray, and/or SJH Elmer Hospital, individually or in combination, entered into financial contracts or relationships with the Medtronic Defendants in which they used and sold to Plaintiff and other patients products manufactured and sold by the Medtronic Defendants and

profited thereby by receiving kickbacks, discounts, "incentives" or other financial inducements to use the Medtronic products.

24. Such financial arrangements between and among the Defendants impacted their judgment in selection and implantation of Medtronic products even where such surgeries were unnecessary or contraindicated, and increased the risk of harm to the patients, including Plaintiff, and such harm occurred.

25. There is no indication in the records or operative reports of Defendant Shah that he informed Plaintiff thoroughly of the risks of the above procedures, including but not limited to: hardware or equipment failure; migration of hardware either as the result of malplacement, malpositioning, or misalignment of the hardware or other causes, failure of the fusion due to BMP or other side effects, or other issues and complications related to the hardware and equipment used in her surgery.

26. There is no indication in the records or reports of Defendant Shah that he advised Plaintiff that the recommended surgery he would perform was either unnecessary or contraindicated in her case, as other physicians later informed her.

27. Following the March 21, 2011 procedure, Plaintiff complained of ongoing and extreme and worsening pain in her back and lower extremities, eventually experiencing the condition known as "foot drop" and other harm resulting from the negligence in surgery and/or the failure of the surgical hardware.

28. On or about May 5, 2011, a CT LS-Spine without contrast was performed at SJC Regional Medical Center in Vineland, New Jersey, as ordered by Dr. Shah, and showed postsurgical laminectomy changes at the L3-4 through L5-S1 levels, with bilateral pedicle screws and rods at L4-S1 and an additional horizontal adjoining bar

at L5; intervertebral disk cages/spacers are present; posterior migration centrally of the L4-L5 spacer and surrounding disk into the ventral epidural space and spinal canal and resultant near moderate canal stenosis was visualized; also seen was posterior migration right paracentrally of the L5-S1 vertebral disk cage/spacer and surrounding ventral epidural region and spinal canal and resultant anterior right-sided canal stenosis; also visualized was moderate bilateral foraminal stenposis at L5-S1 and L4-L5; Extensive streak artifact limits evaluation of the spinal canal at the L4 through S1 levels.

29. Despite the indicated inadequacy of the evaluation on May 5, 2011, there is no evidence that Dr. Shah ordered additional films at that time for clarification.

30. On or about May 18, 2011, Plaintiff was admitted to SJH Elmer Hospital in Elmer, New Jersey, with a diagnosis of L4- to S1 lumbar stenosis status post L4 to S1 TLIF for a revision surgery.

31. The orthopedic resident dictated the discharge summary for Dr. Shah, noting that the cage had slipped posteriorly and needed to be revised.

32. Following surgery, she was maintained on antibiotics and DVT prophylaxis, given a back brace, physical and occupational therapy, and discharged to rehab, to follow up with Dr. Shah in 7 to 10 days.

33. Defendant Gray dictated the history and physical for Dr. Shah, noting patient was "Status post L4-S1 decompression and insufflated effusion with migration of interbody spaces at L4-L5 and L5-S1, with a resultant neuro test of 3-5 on right EHL and peroneal with right-sided lumbar radiculopathy," and further noted the

impression of lumbar stenosis L4-L5 right side and planned to go forth with revision lumbar decompression fusion at levels L4-S1 with exploration of fusion mass;

34. On or about May 18, 2011, Defendant Shah performed a revision surgery on Plaintiff's lower back.

35. The operative report stated a pre-operative and post-operative diagnosis of "failed hardware of lumbar spine", and procedures by Dr. Shah with assistance by PA-C Gray were listed as: lumbar laminectomy, revision of bilateral, L4/5 and L5/S1; lumber instrumentation, removal of hardware, instrumentation of hardware, posterolater "effusion" (sic), lumbar autograft, lumbar allograft, application of posterior interbody lumbar "effusion" (sic), Application of allograft anterior lumbar, Application of biomechanical device interspace, all at L4-L5 and/or L5-S1, with intraoperative fluoroscopy and neuro monitoring with electromyogram and somatosensory evoked potential.

36. Implant equipment noted to be used in the report of May 18, 2011 were Legacy screws, Capstone antibody device, and demineralized bone matrix.

37. Intraoperative findings noted in the report of May 18, 2011, were Hardware failure at L5/S1 and well-fixed implant L4/5.

38. During the procedure, screws and rods were removed and an extractor was used to remove the loose and migrated Capstone interbody spacer; a new Capstone spacer was inserted.

39. It is unclear in the records what was done with the defective equipment after removal and what was reported to the manufacturer or any government agency concerning the equipment.

40. During the procedure, Dr. Shah shaved the space of the L5/S1 from 10 mm up to 12 mm and inserted a 12 mm implant and set screws were applied, deformity was corrected, and the wound was irrigated, bone graft applied, and the wound was closed.

41. Cancellous chips item 400150 SN 03510049491137A 30 cc and Serial No. 008 11000721029P 30 cc and DBX putty Item 038050 Serial No. 017091092911030004, 5 cc, were supplied by the Musculoskeletal Transplant Foundation for the procedure.

42. INFUSE Bone Graft (rhBMP-2/ACS) x small kit Lot No. M111055AAJ sterile M7051068012, Manufactured by MEDTRONIC, was identified in the records by label.

43. CAPSTONE Spinal System, REF 2991222, LOT No. H10J1638 size 12 X 22 mm implant, with handwritten note "Implant" was identified in the records by label.

44. On May 19, 2011, the day after the surgery but before her discharge on May 20, 2011, Plaintiff complained to the physical therapist of pain in her back at rest and "no feeling" in her right lower extremity.

45. Plaintiff was prematurely discharged from the hospital on May 20, 2011 without adequate investigation into her ongoing and new complaints prior to discharge.

46. Complete medical records have been requested from the Defendants Shah, Premier Orthopedic Associates, and SJH Elmer Hospital but Plaintiff has not received complete and accurate records, including any personnel lists of those who participated

in the care and treatment of Plaintiff, and demand is hereby made for complete and accurate production of such records, with all rights reserved to amend this complaint with such additional parties and claims as may be revealed when Plaintiff gains possession of such records.

47. As a direct and proximate result of the negligence and medical malpractice of the healthcare Defendants and in combination and concurrence with the unreasonable dangerousness and defectiveness of the medical and surgical products which malfunctioned or were otherwise defective when they left the control of the MEDTRONIC Defendants, Plaintiff sustained serious, permanent and disabling injuries to her back, hip, and legs, including but not limited to: failure of surgical hardware and implants requiring additional surgery to remove and replace the hardware; aggravation of her preexisting back condition; a condition of "drop foot" which cannot be cured and will permanently disable Plaintiff in her activities; ongoing severe pain in her back and radiculopathy into her buttocks and lower extremities; avascular necrosis of the hip requiring surgical replacement; nerve damage, and other injuries and conditions.

48. As a further direct and proximate result of the negligence of the healthcare Defendants and the defective products of the Medtronic Defendants, Plaintiff has sustained substantial special damages including medical bills in the past and future, and incurred additional liens and subrogation interests which have to be accounted for out of any recovery made from responsible Defendants herein.

49. As a further direct and proximate result of the negligence of the healthcare Defendants and the defective products of the Medtronic Defendants, Plaintiff has

sustained in the past and will sustain in the future lost wages and lost earning capacity.

50. As a further direct and proximate result of the negligence of the healthcare Defendants and the defective products of the Medtronic Defendants, Plaintiff has sustained substantial general damages for severe and continuing pain and suffering, loss of enjoyment of life in the past and future, disability, physical deformity, scarring, impairment of functional abilities, embarrassment, inconvenience, humiliation, and other unliquidated damages for the harm caused to her.

51. The negligent acts and omissions of all of the Defendants and the defectiveness of the products combined and commingled to cause, contributed to cause and were substantial factors in causing the harm, injuries and damages to the Plaintiff.

52. Defendants are or may be liable to the Plaintiff on theories of direct liability as well as vicarious liability for the acts and omissions of their actual or ostensible agents, servants and employees, and the doctrine of ***respondeat superior*** is claimed herein.

53. The healthcare Defendants, at all times relevant, had sole custody and control of all instrumentalities used in the surgeries upon Plaintiff, while Plaintiff was under anesthesia, and the harm complained of normally does not occur without acts or omissions in negligence, and therefore, the doctrine of ***res ipsa loquitor*** is claimed herein.

54. At all times relevant herein, Dr. Shah was in charge as the surgeon during the surgeries on Plaintiff which took place on March 21, 2011, and May 18, 2011,

and had a duty to adequately supervise the physician's assistant, residents, nurses, and other assistants so as to properly care for Plaintiff.

55. At all times relevant herein, Dr. Shah and PA-C Gray were employed by Defendants Premier Orthopaedic Associates Surgical Center, LLC, and/or Premier Orthopedic Associates of South Jersey, and therefore, the Premier Defendants are or may be liable for their negligent acts and omissions.

56. At all times relevant herein, there were involved in the activities of the healthcare Defendants and in the activities of the Medtronic Defendants, unidentified individuals and businesses entities, herein fictitiously named as "John Doe Corporations A through J" and "John Does A through J" , who are or may be liable to the Plaintiff along with the named Defendants on the basis of each of the Counts below, and each Count is intended to include such business entities and individuals, reserving Plaintiff's right to discover their identities and amend her pleading to name them when revealed.

COUNT I: NEGLIGENCE: MEDICAL MALPRACTICE: PLAINTIFF V. DEFENDANT RAHUL V. SHAH, M.D.

57. Plaintiff incorporates by reference all of the preceding paragraphs as though fully set forth herein.

58. Defendant Rahul V. Shah had duties to the Plaintiff as her orthopedic surgeon, first, to do no harm, and otherwise, to perform the subject surgeries in a manner which met the standards of professional care for a specialist in his field.

59. Defendant Shah breached his duties to the Plaintiff, causing her harm.

60. The negligent acts and omissions of Defendant Shah included but were not limited to the following:

a) Performing an unnecessary or contraindicated surgery on Plaintiff's back;

b) Doing inadequate investigation into the potential risks and consequences of performing the surgeries in March 2011 and May 2011;

c) Using the wrong size of Capstone spacer;

d) Misplacing, misaligning, or malpositioning the surgical implants so that they were more likely to fail;

e) Replacing a failed device with a larger size device which also failed;

f) Failing to involve a competent surgical assistant in the March 2011 and May 2011 surgeries;

g) Permitting an incompetent surgical assistant to participate in Plaintiff's surgeries;

h) Failing to obtain adequate consultations before performing surgery;

i) Operating on a poor surgical candidate for financial interest and gain;

j) Implanting surgical hardware in the Plaintiff which was an off-label use without adequately warning and advising the Plaintiff of potential risks and side effects and failures;

k) Failing to adequately advise Plaintiff and obtain her informed consent concerning the potential for product failure and the impact of product failure on her ability to recover and improve after surgery, reducing her chance to recover.

61. The above negligent acts and omissions fell below the acceptable standards of care for an orthopedic surgeon in the relevant community and were substantial factors in causing harm to the Plaintiff.

WHEREFORE, Plaintiff asks this court to enter judgment in her favor and against the Defendant(s) in an amount in excess of $125,000.00, exclusive of interest and costs, and such other and further relief, including punitive damages, to which the court may deem her entitled.

COUNT II: BATTERY: LACK OF INFORMED CONSENT: PLAINTIFF V. DEFENDANT RAHUL V. SHAH, M.D.

62. Plaintiff incorporates by reference all of the previous paragraphs as though fully set forth herein.

63. Defendant Shah had a duty to advise Plaintiff of all of the significant risks and side effects of the subject surgeries, including the risks of failure of the implanted hardware which he selected and placed, and including the increased risk of harm from improper sizing and placement of such hardware.

64. Defendant Shah did not reveal to Plaintiff his financial arrangements with the Medtronic Defendants to use their products regardless of the harm to Plaintiff.

65. Defendant failed to so advise Plaintiff, depriving her of the opportunity of given fully informed consent to the surgeries.

66. As a result of this failure of the Defendant, he committed a battery upon the Plaintiff, thereby causing her harm.

67. Plaintiff would not have consented to the surgeries complained of had she been fully apprised of all material and significant risks withheld from her knowledge.

WHEREFORE, Plaintiff asks this court to enter judgment in her favor and against the Defendant(s) in an amount in excess of $125,000.00, exclusive of interest and costs, and such other and further relief, including punitive damages, to which the court may deem her entitled.

COUNT III: NEGLIGENCE: CORPORATE LIABILITY: PLAINTIFF V. DEFENDANTS PREMIER ORTHOPAEDIC ASSOCIATES SURGICAL CENTER, LLC AND SOUTH JERSEY HEALTHCARE DBA/TA SJH ELMER HOSPITAL

68. Plaintiff incorporates by reference all of the preceding paragraphs as though fully set forth herein.

69. Defendants Premier Orthopedic Associates Surgical Center and South Jersey Healthcare DBA/TA SJH Elmer Hospital had, in addition to their vicarious duties for their agents and employees, independent duties to the Plaintiff with respect to the management and operation of the hospital, including the selection, training and supervision of actual and ostensible agents, servants and employees, granting of privileges, and the establishment of adequate policies, procedures, and practices in their facilities to ensure the safety of patients, the meeting of reasonable standards of care, prevent medical malpractice, and create a reasonably safe and secure environment for the care and treatment of patients, including Plaintiff, herein.

70. Defendants did not advise the Plaintiff that the persons participating in her operations had limited experience and credentials which would substantially increase the risk of harm coming to her resulting from the surgeries.

71. Defendants breached said duties and caused harm to the Plaintiff.

WHEREFORE, Plaintiff asks this court to enter judgment in her favor and against the Defendant(s) in an amount in excess of $125,000.00, exclusive of interest and costs, and such other and further relief, including punitive damages, to which the court may deem her entitled.

COUNT IV: PRODUCT LIABILITY UNDER THE COMMON LAW: PLAINTIFF V. DEFENDANTS MEDTRONIC SOFAMOR DANEK USA, INC., MEDTRONIC SPINE, LLC, MEDTRONIC USA, INC., AND MEDTRONIC, INC.

72. Plaintiff incorporates by reference all of the preceding paragraphs as though fully set forth within.

73. Defendants Medtronic Sofamor Danek USA, Inc., Medtronic Spine, LLC; Medtronic USA ,Inc., and Medtronic, Inc., manufactured, remanufactured, refurbished, inspected, tested, distributed, marketed, assembled, packaged, labeled, warranted, supplied and/or sold medical and/or surgical products, devices and/or goods which were used or implanted into the Plaintiff during the surgeries performed by Dr. Shah in March and May 2011 upon Plaintiff Maria Mendez.

74. The Medtronic Defendants, each or in combination, supplied certain medical and/or surgical products to Plaintiff's surgeon and/or surgeon's practice and/or hospital and/or surgical center, in a defective and unreasonably dangerous condition, unexpected by the consumer or plaintiff, containing elements which made it unreasonably unsafe and lacking elements which would have made it reasonably safe, and the Defendants should be held to the standards of strict liability, and furthermore the Defendants were negligent in the acts and omissions they committed, as follows:

a) The medical products implanted into the plaintiff were inadequately tested, inspected, designed, manufactured, labeled, packaged, and sold without adequate instructions, warnings, and labels, all in violation of the laws, statutes and regulations of the Food and Drug Administration for Class II devides under the Medical Devices Act and attendant regulations.

b) The medical products implanted into the plaintiff failed to incorporate adequate warnings, instructions, and labels.

c) There were inadequate warnings and instructions to surgeons for implanting devices in a safe and proper method.

d) Defendants designed and manufactured the surgical products in a defective and unreasonably dangerous manner which created an unreasonable risk of harm to the patients.

e) Defendants manufactured the surgical products in a negligent manner which created an unreasonable risk of harm to the patient, including Plaintiff.

f) Defendants failed to adequately train and instruct surgeons in the risks and potential harm which could befall patients and failed to instruct surgeons in how to adequately warn patients of the harm which could be caused by failure of the hardware and by malpositioning and malplacement of the hardware in the patient.

g) Defendants failed to warn physicians and patients of complications, side effects, and hazards which they knew/should have known would cause harm.

75. The defective and unreasonably dangerous condition of the product(s) was/were a direct and proximate cause , contributed to cause, and was/were a substantial factor in causing and was/were a concurring cause with other factors in causing the injuries and damages to the Plaintiff as described herein.

WHEREFORE, Plaintiff asks this court to enter judgment in her favor and against the Defendant(s) in an amount in excess of $125,000.00, exclusive of interest and costs, and such other and further relief, including punitive damages, to which the court may deem her entitled.

COUNT V: PRODUCT LIABILITY UNDER THE NEW JERSEY PRODUCT LIABILITY ACT, M.S.STAT. § 2A:58C-1 et seq.

76. Plaintiff incorporates by reference each of the foregoing paragraphs as though fully set forth herein.

77. The New Jersey Legislature promulgated the Product Liability Act in order to clarify certain aspects of product liability law in the state and not to supercede or abrogate provisions of the common law which provide remedies for and protect consumers from the hazards of unreasonably dangerous products.

78. The New Jersey common law and statutory law claims herein parallel federal requirements as to medical devices and therefore are not pre-empted.

79. Section 2A:58C-2 of the Act states that a manufacturer or product seller shall be liable to the plaintiff if the plaintiff shows by a preponderance of the evidence that the product was "not reasonably fit, suitable or safe for its intended purpose" because it (a) deviated from design specifications or from other units; (b) failed to contain adequate warnings or instructions or (c) was designed in a defective manner.

80. The Medtronic Defendants are liable to plaintiff in this case as manufacturers, sellers, designers, marketers, labelers, packagers and distributors of the products which caused plaintiff personal injuries, damages and harm.

81. The Medtronic Defendants participated in the manufacture and sale of surgical products implanted in the plaintiff including the Capstone spinal system, Infuse bone Graft, CD Horizon Legacy screws and other products which were

defective and unreasonably dangerous to the Plaintiff in that they failed or malfunctioned and were not fit for the purpose for which they were intended.

82. The subject products were defective in that they were not accompanied by adequate warnings and instructions concerning the hazards they posed to patients as required by the FDA requirements for Class II devices of this nature.

83. The subject products were defective in that they were negligently designed in violation of FDA requirements.

84. The defects in the products existed at the time they left the control of the manufacturers and sellers and entered into the stream of commerce and the condition of the product remained substantially the same until the time of the events complained of herein.

85. The above-described defects, singly or in combination, directly and proximately caused the harm to plaintiff alleged herein.

WHEREFORE, Plaintiff asks this court to enter judgment in her favor and against the Defendant(s) in an amount in excess of $125,000.00, exclusive of interest and costs, and such other and further relief, including punitive damages, to which the court may deem her entitled.

COUNT VI BREACH OF EXPRESS WARRANTY:
PLAINTIFF V. MEDTRONIC SOFAMOR DANEK USA, INC., MEDTRONIC SPINE, LLC, MEDTRONIC USA, INC., MEDTRONIC, INC.

86. Plaintiff incorporates by reference all of the preceding paragraphs as though fully set forth herein.

87. During the time period before Plaintiff's surgery, the Medtronic Defendants participated in an aggressive marketing campaign, including incentives,

inducements, and kickbacks paid to physicians, hospitals, surgical centers and others, who would agree to push Medtronic's products for use in spinal surgeries on patients, which included statements as to the safety of their products (identified hereinabove) which dismissed or downplayed risks of such use, off-label use, or use in patients for whom the surgery would be unnecessary, contraindicated, experimental, or ill-advised, such as Plaintiff herein.

88. Such statements in Medtronic's literature, in television or other advertising, and/or made by sales and marketing personnel constituted express warranties for which the Medtronic defendants should be held liable.

89. Such statements were made in public advertising as well as to physicians, physician's associations, and hospitals or surgical centers, by-passing such professionals to reach consumers generally.

90. The Medtronic Defendants (each or in combination) breached such warranties in the case of use of their spinal surgery products in Plaintiff's back.

91. The Medtronic Defendants' breach caused irreparable harm to the Plaintiff, including the aggravation of her previously existing back condition, the new conditions of permanent nerve and muscular and other damage and the condition of "drop foot" which she did not have before the surgeries performed by Dr. Shah in March and May of 2011.

WHEREFORE, Plaintiff asks this court to enter judgment in her favor and against the Defendant(s) in an amount in excess of $125,000.00, exclusive of interest and costs, and such other and further relief, including punitive damages, to which the court may deem her entitled.

COUNT VII: BREACH OF CONTRACT:
PLAINTIFF V. DEFENDANTS SHAH, PREMIER ORTHOPAEDIC ASSOCIATES SURGICAL CENTER, PREMIER ORTHOPEDIC ASSOCIATES OF SOUTH JERSEY, GRAY, AND SOUTH JERSEY HEALTHCARE DBA/TA SJH ELMER HOSPITAL

92. Plaintiff incorporates by reference all of the preceding paragraphs as though fully set forth herein.

93. Defendants Shah, Premier Orthopaedic Associates Surgical Center, Premier Orthopedic Associates of South Jersey, Gray, and SJH Elmer Hospital, entered into contracts with the Plaintiff Maria Mendez for her care and treatment, both in writing and by express verbal statements.

94. The contracts entered into were contracts of adhesion as Plaintiff relied entirely upon the Defendants' representations as to the appropriateness, quality, and standards of care that she would receive during the surgeries in March and May of 2011 including any follow-up care and treatment from these providers and their staffs.

95. Consideration was paid by the Plaintiff to these healthcare providers, both with certain benefits paid on her behalf and in the outstanding balances for which she is or may be held liable.

96. Plaintiff placed herself in the care of the Defendants and complied with all requirements they placed on her.

97. Defendants breached their contracts with the Plaintiff by failing to provide reasonably safe and competent care during her surgeries, including the provision of

competent and qualified medical personnel to care for her and not to perform unnecessary, ill-advised, or contraindicated surgery without her informed knowledge and consent.

98. Defendants further breached their contracts with the Plaintiff by failing to adequately train, instruct, and supervise medical personnel.

99. Defendants further breached their contracts with the Plaintiff by failing to disclose their financial relationships with and incentives received from sales representatives of the Medtronic Defendants to use their products even when ill-advised, unnecessary and/or contraindicated.

100. Such breaches of their contracts caused grievous injuries, aggravations of pre-existing conditions, and irreparable harm to the Plaintiff, all as set forth hereinabove.

WHEREFORE, Plaintiff asks this court to enter judgment in her favor and against the Defendant(s) in an amount in excess of $125,000.00, exclusive of interest and costs, and such other and further relief, including punitive damages, to which the court may deem her entitled.

COUNT VIII: FRAUDULENT CONCEALMENT:
PLAINTIFF V. DEFENDANTS SHAH, PREMIER ORTHOPAEDIC ASSOCIATES SURGICAL CENTER LLC, PREMIER ORTHOPEDIC ASSOCIATES OF SOUTH JERSEY, AND SJH ELMER HOSPITAL

101. Plaintiff incorporates by reference all of the preceding paragraphs as though fully set forth herein.

102. Under New Jersey law, healthcare providers are required to produce a true, unaltered, and complete copy of a patient's chart or records upon request by the patient or patient's representative.

103. Plaintiff's representatives herein requested copies of the medical records on her behalf from Defendants Shah, Premier Orthopaedic Associates Surgical Center, Premier Orthopedic Associates of South Jersey, and SJH Elmer Hospital.

104. To date, Plaintiff's representative has not received true, unaltered, and complete copies of the requested records in response to Plaintiff's proper requests, including an executed HIPAA-compliant authorization for the release of the records.

105. It is believed and therefore averred that the named providers are fraudulently concealing the records in order to deprive plaintiff of her rights to investigate thoroughly and pursue her potential claims against them, individually or in combination.

106. Said records were and are material to the proper pursuit of this litigation.

107. Said records were and are in the possession of Defendants.

108. Defendants have intentionally withheld, altered and/or destroyed the evidence to prevent plaintiff's representatives from a thorough and accurate investigation into her claims.

109. Plaintiff preserves her rights to present evidence of her damages in the underlying action for medical negligence and/or product liability as the litigation progresses.

WHEREFORE, Plaintiff respectfully requests the appropriate instructions to the jury at the appropriate time and upon appropriate proof of fraudulent concealment as to each or all of the named defendants or those fictitiously named individuals or corporations later identified.

ADDITIONAL CLAIM FOR PUNITIVE DAMAGES FOR COUNTS I through VI and VIII:

110. Plaintiff incorporates by reference all of the preceding paragraphs as though fully set forth herein.

111. Punitive damages claims are not a separate cause of action but an additional claim for damages above and beyond compensatory damages, which are separately demanded as a convenience and for clarity, should the evidence warrant an instruction by the court to the jury under the heightened standard of judging the conduct of defendants.

112. The conduct of the Defendants was outrageous in that it was malicious, wanton, willful, oppressive and/or showed a reckless indifference to the interests, life, and safety of the Plaintiff, entitling Plaintiff to an award of punitive damages, over and above his compensatory damages in order to punish the Defendants for their outrageous misconduct and to deter the Defendants and others from committing similar acts.

113. The specific act(s) or omission(s) warranting an award of punitive damages are: selling and distributing medical/surgical devices without adequate warnings and instructions as to the serious injuries which could occur when Defendant(s) knew specifically of the exact hazard which caused plaintiff and others serious injuries.

114. Under the New Jersey Punitive Damages Act, 2A:15-5.9 *et seq.*, Defendant(s) acts and omissions caused the harm suffered by plaintiff and they were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions, and/or

defective products, in that there was a significant likelihood that serious harm would arise from the conduct or products, and that Defendant(s) was/were highly aware that such reckless disregard would result in serious harm to patients, and the conduct of the Defendant(s) continued for an unreasonable period of time even after it/they knew of the harm being caused by its/their conduct and/or products.

WHEREFORE, Plaintiff respectfully requests that this Honorable Court issue judgment in his favor and against all Defendants, individually, jointly, and severally, in a sum in excess of the jurisdictional limit of this court, exclusive of interest and costs, over and above compensatory damages, as and for punitive damages, to punish defendants' outrageous and reckless disregard of the lives and safety of others, and to deter others from similar conduct, together with such other relief as this Court may deem appropriate.

JURY OF 12 DEMANDED FOR TRIAL.

Attorneys' Lien Requested.

Respectfully submitted,
Rooney & Rooney

Dated: March 11, 2013

s/Michael T. Rooney
MR2834
Michael T. Rooney, Esq.
Celia Ann Rooney, Esq.
Attorneys for Plaintiff